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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,998	09/18/2003	J. Oliver Dolly	17259-CON (B07)	1940

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EXAMINER

FALK, ANNE MARIE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/667,998	Applicant(s) DOLLY ET AL.	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-24 are pending in the instant application.

Although Claims 13-24 each depend from Claim 11, it is assumed that the claims are intended to depend from Claim 12, given that the majority of the factors recited in Claims 13-24 fall outside the scope of Claim 11, which reads on only IGF-I and IGF-II.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a method for extending the effective time period during which tissue treated with a clostridial toxin is paralyzed comprising administering a composition comprising an agent able to prevent the neuroregenerative activity of a polypeptide as recited in the claims (various neurotrophic factors), classified in class 514, subclass 44 and class 424, subclass 130.1.
- II. Claims 12-24, drawn to a method for stimulating the outgrowth of neural sprouts from damaged neural tissue comprising contacting said tissue with a composition comprising a polypeptide which comprises a neurotrophically active domain derived from an agent selected from the various neurotrophic factors recited in the claims, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the inventions are drawn to mutually exclusive and independent methods. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have opposite

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effects. The method of the invention of Group I is directed to inhibiting the activity of a neurotrophic factor by administering an inhibitor, whereas the method of the invention of Group II is directed to increasing the activity of a neurotrophic factor by directly administering the factor (or a fragment thereof). Each of these methods require physically and functionally distinct elements. The methods require the use of different starting materials, have different modes of operation, and produce distinct outcomes. The method of the invention of Group I prevents the regeneration of neural tissue damaged by clostridial toxin, whereas the method of the invention of Group II stimulates neural sprouting from damaged neural tissue. The inventions are not disclosed as being used together. Thus, the method of the invention of Group I is patentably distinct from the method of the invention of Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper. The search and examination of each invention group would constitute a serious burden on the Office, as each group requires a separate search and consideration of issues separately applicable to each group.

Each of the inventions of Groups I and II requires consideration of separate issues relating to assessment of novelty, obviousness, utility, written description, and enablement. For example, the method of the invention of Group I requires consideration of issues relating to enablement for extending the period of paralysis induced by clostridial toxin (i.e., preventing neural regeneration), whereas the method of the invention of Group II requires consideration of issues relating to enablement for inducing neural regeneration. Given the very different inventions, the searches required for the inventions of Groups I and II are not coextensive. For example, a search for methods of inhibiting the activity of the various neurotrophic factors recited in the claims of the invention of Group I would not likely identify art

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teaching the method of the invention of Group II, which is a method of stimulating neural regeneration. Additional searching would be required to cover the invention of Group II. Likewise, a search for the method of the invention of Group II would not likely identify art teaching the method of the invention of Group I, directed to inhibiting neurotrophic factors and their regenerative activities. Additional searching would be required to cover the invention of Group I. Thus, search and examination of both of the instantly claimed inventions in a single patent application constitutes a serious burden on the Office.

With regard to burden, MPEP § 808.02 states that, to establish that there would be a serious burden on the examiner if restriction is not required,

“the examiner must show by appropriate explanation one of the following:

(A) **Separate classification thereof:** This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.” (emphasis original)

Thus, to establish that a serious burden exists, it is sufficient to show separate classification of the inventions. The instant inventions have separate classifications and require separate search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Election of Species

Part 1. Upon election of Group I, Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following agent classes, as set forth in Claim 6:

- A. An antibody able to selectively bind said polypeptide.
- B. A competitive inhibitor of said polypeptide.

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- C. A compound able to selectively prevent the expression of a gene encoding said polypeptide.
- D. A binding protein other than an antibody.
- E. A ribozyme.
- F. A nucleic acid encoding an inactive growth factor receptor able to bind said growth factor.

The different classes of agents as outlined in the species election requirement A-F represent distinct inventions because they are drawn to different agents that are structurally and functionally distinct, having very different modes of action. The different agent classes require separate searches. The agents are not so related as to be considered obvious variants. Furthermore, there is nothing on the record to suggest that the agents are obvious variants.

Part 2. Upon election of Group I or II, Applicant is required to elect one of the species listed below. This application contains claims directed to the following patentably distinct species of the claimed invention, covering the following polypeptides:

- A. IGF I
- B. IGF II
- C. Ciliary neurotrophic factor
- D. NT-3
- E. NT-4
- F. Brain-derived neurotrophic factor
- G. Leukemia inhibitory factor
- H. Tenascin-C
- I. Ninjurin
- J. Neural cell adhesion molecule
- K. Neural agrin

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The different species of neurotrophic proteins as outlined in the species election requirement A-K represent distinct inventions because they are drawn to different proteins requiring different searches for each method of use. The proteins are not so related as to be considered obvious variants. Furthermore, there is nothing on the record to suggest that the proteins are obvious variants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species associated with the elected invention, even though this requirement is traversed.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named

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inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Thursday from 10:00 AM to 8:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER